

## **NCI and VA Make It Easier for Veterans To Enter Studies, Get Advanced Care for Cancer**

Veterans gained expanded access to promising new approaches to cancer care under the terms of a clinical trials agreement announced in January 1997 by the National Cancer Institute (NCI) and the Department of Veterans Affairs (VA). According to the agreement, VA will provide coverage for eligible veterans to participate in a broad range of NCI clinical trials across the country.

The new partnership paves the way for more NCI clinical trials to be carried out in VA facilities. In addition, VA will pay the medical care costs of veterans who enroll in NCI trials in non-VA facilities in selected cases.

“The agreement expands the already productive relationship between VA and NCI,” said VA’s Kenneth W. Kizer, M.D., Under Secretary for Health. “It means greater access to the full range of promising new treatments for cancer.”

The agreement went into effect January 1, 1997, and covers NCI-sponsored prevention, diagnostic, and treatment studies around the country. Under treatment trials, the agreement includes both the smaller, early trials of new approaches, known as phase I and phase II trials, and the much larger phase III trials that compare different treatment approaches.

“Developing an expanded pool of VA cancer researchers will strengthen our clinical research program across the board,” said Robert Wittes, M.D., Director of NCI’s Division of Cancer Treatment, Diagnosis, and Centers. “We expect this agreement to lead to more timely answers to some major questions about preventing, diagnosing, and treating cancer.”

The new agreement is part of an ongoing effort at NCI to ensure continued and expanded access to clinical trials by eliminating barriers to patient enrollment. This agreement also reflects VA’s recent efforts to expand its partnerships and formal relationships with non-VA health care related organizations.

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## Questions and Answers About the NCI/VA Agreement on Clinical Trials

The National Cancer Institute (NCI) and the Department of Veterans Affairs (VA) have signed an Interagency Agreement that is intended 1) to increase the access of eligible veterans to all phases of NCI-sponsored clinical trials and 2) to provide VA clinical researchers with expanded opportunities to participate in clinical cancer research.

### 1. What is a clinical trial?

Cancer clinical trials are research studies conducted with people to find better ways to prevent, diagnose, and treat cancer. These studies answer important scientific questions that can lead to future advances in cancer treatment. Patients who choose to participate in studies do so in the hopes of being cured, living longer, or contributing to research efforts that may help others.

### 2. Which clinical trials are covered by the NCI/VA agreement?

The agreement covers the full range of NCI-sponsored clinical trials, including prevention, diagnostic, and treatment studies.

*Prevention clinical trials* look at lifestyle changes or drugs that may help prevent cancer. For example, an NCI trial has recently shown that a drug can reduce the incidence of breast cancer in some women at high risk.

*Diagnostic clinical trials* look at ways of detecting cancer or finding out more about the cancer, which can help guide treatment. One current NCI trial, for example, is designed to find the best way to manage the mild abnormalities that often show up on routine screening tests (Pap tests) for cervical cancer.

*Treatment clinical trials* may study new drugs or other ways of treating cancer, or they may look at new combinations of established treatments. Included in the NCI/VA agreement are phase I treatment trials, which test the safety of a treatment; phase II trials, which determine whether a treatment is effective in various kinds of cancer; and the larger phase III trials, which compare a widely accepted or “standard” treatment with a new treatment that appeared promising in phase II studies. One example of a current treatment trial is a phase II study of the drug paclitaxel in combination with cisplatin to treat advanced or relapsed lung cancer.

### **3. Which trials are defined as “NCI-sponsored”?**

NCI-sponsored trials, for the purpose of the agreement, are:

- Trials reviewed and approved by NCI staff;
- Studies conducted by NCI cooperative clinical trial groups, which are networks of institutions that jointly carry out large clinical trials following the same protocols;
- Studies conducted in clinical and comprehensive cancer centers under an NCI-approved protocol review and surveillance mechanism; and
- Protocols performed under the direct support of an NCI peer-reviewed grant.

### **4. Which veterans are covered by the agreement?**

Veterans covered are those who fall into the “mandatory” category under legislation passed by Congress. These include:

- Service-connected veterans (those with a VA determination of a service-related health problem);
- Former prisoners of war;
- Veterans who were exposed to herbicides while serving in Vietnam, to ionizing radiation during atmospheric testing and during the occupation of Hiroshima and Nagasaki, or to an environmental hazard while serving in the Persian Gulf Theater and need treatment for a condition that might be related to such exposures;
- Veterans receiving a VA pension;
- Veterans of World War I;
- Veterans eligible for Medicaid; and
- Veterans who are non-service-connected and whose income is \$21,001 or less if single with no dependents, or \$25,204 or less if married or single with one dependent, plus \$1,404 for each additional dependent.

### **5. Where can veterans enroll in NCI clinical trials?**

Veterans will be able to enroll in trials at participating VA facilities and, in selected cases, in non-VA institutions. VA will define the circumstances under which patients will enroll in trials in non-VA facilities.

## **VA Medical Centers**

Fifty-two of the 173 VA medical centers around the country are already affiliated with NCI's cooperative groups, the networks of institutions that carry out joint clinical trials. More are expected to join the NCI cooperative groups as a result of the agreement. In addition, some VA medical centers that are affiliated with major academic medical centers are already participating actively in NCI-sponsored early clinical trials of new agents. This agreement calls for more extensive participation in the early clinical trials program by VA.

## **Non-VA Medical Centers**

Under special circumstances, such as trials of particular importance to the VA or trials of rare tumor types, VA may offer mandatory veterans access to NCI-sponsored clinical trials in non-VA facilities.

### **6. How do veterans and their doctors find out what trials are enrolling patients and where they are located?**

NCI maintains a database of clinical trials as part of its Physician Data Query (PDQ) system. PDQ provides comprehensive information on NCI-sponsored trials enrolling patients throughout the country. The database is updated monthly and provides the latest information on eligibility for clinical trials as well as physicians and hospitals participating in the trials. NCI has added a feature to PDQ that lets users search by VA facilities to identify the specific trials in which the facilities are participating.

Patients and the general public can call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) to request a customized search of PDQ. Callers can ask, for example, for a search specific to a geographic location or a certain mode of treatment, as well as to the type and stage of cancer. Health professionals can call the PDQ/CANCERLIT Service Center at 1-800-345-3300 to request a customized search, or they can send an E-mail to the PDQ/CANCERLIT Service Center ([pdqsearch@icic.nci.nih.gov](mailto:pdqsearch@icic.nci.nih.gov)). In addition, NCI has developed a World Wide Web page that allows any user to search the PDQ database directly (<http://cancernet.nci.nih.gov>).

### **7. What other joint activities does the agreement establish?**

NCI and VA also will establish closer cooperation in planning future trials and in addressing economic research questions, including cost effectiveness evaluation. The agreement can be accessed on the VA's World Wide Web page, Veterans Health Administration Cancer Clinical Trials (<http://www.va.gov/cancer.htm>), and on NCI's CancerNet™ website (<http://cancernet.nci.nih.gov>). More information about clinical trials is available on NCI's clinical trials website at <http://cancertrials.nci.nih.gov> on the Internet.

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## **Sources of National Cancer Institute Information**

### **Cancer Information Service**

Toll-free: 1-800-4-CANCER (1-800-422-6237)

TTY (for deaf and hard of hearing callers): 1-800-332-8615

### **NCI Online**

#### ***Internet***

Use <http://www.cancer.gov> to reach NCI's Web site.

#### ***CancerMail Service***

To obtain a contents list, send e-mail to [cancermail@icicc.nci.nih.gov](mailto:cancermail@icicc.nci.nih.gov) with the word "help" in the body of the message.

### **CancerFax® fax on demand service**

Dial 301-402-5874 and listen to recorded instructions.

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